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| 09/857,841      | 08/30/2001  | Rong-Xiang Fang      | 2577-109            | 2938             |

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EXAMINER

FOX, DAVID T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1638

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/857,841

Applicant(s)

FANG ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 10-14, 19, 21, 22 and 25-32 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 and 24 is/are allowed.
- 6) ☒ Claim(s) 6-9, 15-18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

*PD*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments of 29 March 2005 have overcome the rejection under 35 USC 101.

The application should be reviewed for errors. Errors appear, for example, in claim 8, line 1, where "nucldic" should be replaced with ---nucleic---.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

This Office action is made non-final in view of the new grounds of rejection applied by the new examiner assigned to this application. The delay in prosecution is regretted. In the Office action below, claim amendments are suggested to overcome rejections. In the interest of saving time and space, the Examiner has only set forth the suggested phrases to be inserted or replaced. The Examiner's suggestions do not comply with 37 CFR 1.121(c), and are not meant to be interpreted as the format which Applicant should employ. All amendments submitted by Applicant should comply with 37 CFR 1.121 (c).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 15-17 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claims 9 and 17 are indefinite in their recitation of "a 35S promoter" as it is unclear what Applicant intends. If intended, insertion of ---CaMV--- before "35S" would obviate this rejection. Support for this amendment may be found on page 11 of the specification, bottom line.

Claim 15 and dependents are indefinite in the recitation of "capable of transforming a plant cell" as it is unclear whether or not the vector actually possesses this characteristic. Thus, the claim does not positively recite a required characteristic. Alternatively, the recitation of "capable of transforming a plant cell" can be viewed as a mere recitation of an intended use, which does not positively recite any structural feature of the vector. Any vector may be "capable of" transforming a plant cell, depending upon the method of transformation being used. If Applicant intends that the vector comprise a gene which can be expressed in the plant cell, then the structural features enabling such expression should be positively recited.

The following amendments would obviate this rejection:

In claim 15, lines 1-2, delete "capable of transforming a plant cell wherein said vector comprises".

In claim 15, line 2, insert --- comprising a plant-expressible promoter operably linked to--- before "a nucleic acid". Support for this amendment may be found in Figure 6, and on page 2 of the specification, lines 8-9 and 14-15.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-7, 15-16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamamoto et al (US 5,618,699).

The claims are drawn to a method of producing a nucleic acid construct comprising the insertion of a first nucleic acid upstream of a second nucleic acid, wherein said first nucleic acid encodes "a" protein of SEQ ID NO:4; vectors comprising said constructs, and plant cells or plants comprising said vectors. "A" protein of SEQ ID NO:4 is interpreted as any portion of SEQ ID NO:4 of any length, including a single amino acid residue.

Hamamoto et al teach a method of producing a nucleic acid construct comprising the insertion of a first nucleic acid, encoding a portion of a viral coat protein, upstream of a second nucleic acid encoding a protein of interest; vectors comprising said constructs; and plant cells comprising said vectors (see, e.g., Figures 4b, 5 and 8; column 1, line 63 through column 4, line 31; column 5, line 8 through column 9, line 38). Said portion of a viral coat protein would inherently comprise at least one amino acid of SEQ ID NO:4.

Replacement of "a protein of SEQ ID NO:4" with ---the protein of SEQ ID NO:4--- would obviate this rejection.

Claims 6-9, 15-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/21018 (ASGROW SEED COMPANY).

The claims are drawn to methods of constructing vectors encoding a protein comprising "a" protein of SEQ ID NO:4 linked to a "protein of interest", wherein the vector additionally comprises a 35S promoter, and wherein the vector comprises bases 6-47 of SEQ ID NO:3; the vectors per se; and plant cells and plants containing them.

ASGROW SEED COMPANY teaches vectors comprising SEQ ID NO:4 under the control of a CaMV 35S promoter, wherein the vector inherently comprises bases 6-47 of SEQ ID NO:3, wherein the vector encodes a cucumber mosaic coat protein; and plant cells and plants transformed therewith (see, e.g., Figure 3; page 6 of the specification, lines 11-15; and claims 23-26 and 30-32). The portion of the gene encoding SEQ ID NO:4 is inherently linked to a portion of the gene encoding the rest of the coat protein, which may be considered a "desired protein of interest".

The following amendments would obviate this rejection:

In claim 6, line 5, replace "said desired protein" with ---a heterologous desired protein---.

In claim 15, line 3, insert ---heterologous--- before "protein of interest".

Basis for these amendments may be found on page 1 of the specification, line 7.

Claims 6-9, 15-18 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Boeshore et al (US 6,127,601 filed 29 September 1997).

The claims are summarized above.

Boeshore et al teach vectors comprising SEQ ID NO:4 under the control of a CaMV 35S promoter, wherein the vector inherently comprises bases 6-47 of SEQ ID NO:3, wherein the vector encodes a cucumber mosaic coat protein; and plant cells and

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plants transformed therewith (see, e.g., Figure 3; column 3 of the specification, lines 32-36; column 8, lines 5-13; column 14, lines 29-67; column 16, lines 9-58; columns 25-28 of the specification, SEQ ID NOS: 5-6; and claims 4 and 19). The portion of the gene encoding SEQ ID NO:4 is inherently linked to a portion of the gene encoding the rest of the coat protein, which may be considered a "desired protein of interest".

The amendments suggested in the rejection immediately above would also obviate this rejection.

Claims 6-9, 15-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamamoto et al (US 5,618,699) in view of each of Boeshore et al (US 6,127,601) and WO 96/21018 (ASGROW SEED COMPANY).

The claims are drawn to methods of making fusion proteins comprising a portion of SEQ ID NO:4, which corresponds to the coat protein gene of strain V34 of cucumber mosaic virus, operably linked to a different protein of interest; vectors encoding the fusion protein; and plant cells and plants containing the vectors; wherein the CaMV 35S promoter and a protein comprising a protein encoded by specific portions of SEQ ID NO:3 are utilized.

Hamamoto et al teach the advantages of fusion constructs comprising an N-terminal portion of a viral coat protein for high expression levels and ease of product recovery, and suggest the use of genes encoding the coat protein from cucumber mosaic virus (see, e.g., column 1, lines 7-12 and 65-67; column 2).

Hamamoto et al do not teach a portion of SEQ ID NO:4 as one of the fusion partners, a portion of SEQ ID NO:3 encoding it, or the use of the CaMV 35S promoter.

Each of Boeshore et al and ASGROW SEED COMPANY teach SEQ ID NO:4, bases 4-47 of SEQ ID NO:3, and the use of the CaMV 35S promoter for the expression of the coat protein of strain V34 of cucumber mosaic virus, as stated above.

It would have been obvious to one of ordinary skill in the art to utilize the method of expressing desired genes as fusion proteins comprising an N-terminal portion of a viral coat protein, as taught by Hamamoto et al; and to modify that method by incorporating the cucumber mosaic virus coat protein and gene encoding it, and the CaMV 35S promoter, taught by each of Boeshore et al and ASGROW SEED COMPANY; as suggested by Hamamoto et al. Choice of fragment of SEQ ID NO:4 would have been the optimization of process parameters.

Claims drawn to methods of making a fusion protein comprising a first protein which consists of SEQ ID NO:4, and further comprising a second heterologous protein, would be deemed free of the prior art, given the unexpectedly high levels of protein expression when only the entire SEQ ID NO:4 is used as the fusion partner, as demonstrated on page 8 of the specification, bottom paragraph; pages 9-10; page 11, lines 2-7 and 16-18; page 12.

Applicant's arguments filed 29 March 2005 have been fully considered but they are not persuasive. Applicant urges that the obviousness rejection is improper, given the failure of the prior art to teach or reasonably suggest a fusion protein comprising all fourteen amino acids of SEQ ID NO:4 operably linked to a heterologous protein. The Examiner maintains that the claims are not so limited, as discussed above.



See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Claims 23-24 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest isolated nucleic acids comprising or consisting essentially of the entire SEQ ID NO:3.

Claims 23-24 are allowed.

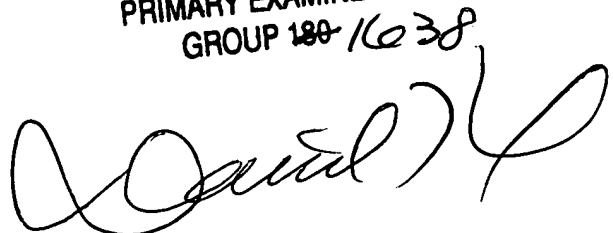
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 30, 2005

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the printed name and group number.